## Remarks

Claims 1-19 have been examined by the Examiner and Applicant respectfully requests reconsideration of these claims in view of the amendments made above and the remarks that follow.

Claim 1 has been amended to essentially incorporate the subject matter of cancelled claim 14 by adding an element to claim 1 that requires there to be a first temperature sensing element that is effective to measure the temperature of the target tissue. In addition, a minor amendment has been made on line 2 of claim 1 to overcome the Examiner's Section 112 rejection. Claim 12 has been amended to characterize the temperature measurement element as a "second" temperature element and to more clearly describe the positioning of this element and its function. This amendment is not made for reasons related to patentability. Claim 13 has been cancelled as being unnecessary in view of the amendment to claim 12, and claim 14 has been cancelled as being unnecessary in view of the amendment to claim 1. Claim 15 has been amended to more clearly explain the function of the pressure measurement element and the amendments to this claim are not related to patentability. Claim 16 has been canceled as being unnecessary in view of the amendments to claim 15.

New claims 46 and 47, which depend from claims 1 and 9, respectively, have been added. In addition, new independent claim 48 has been added. This claim is similar to original claim 1, except that it requires that the implantable member be made of a shape memory material that can be deformed to a first shape upon application of a force and which returns to an at-rest shape upon removal of the force. New claim 49 has also been added. This claim is similar to original claim 1, except that it requires the presence of a temperature sensing element that is disposed within the lumen and that is effective to measure the temperature of any fluid within the lumen.

No new matter is added by any claim amendment or new claim.

### The §112 Rejection

Claims 1-19 stand rejected pursuant to the second paragraph of 35 U.S.C. 112 as being indefinite. The Examiner asserts, in particular, that the term "the tissue" in lines 2-3 of claim 1

lacks sufficient antecedent basis. This rejection is obviated by the amendment to claim 1, discussed above, which, in line 2, characterizes the tissue as "target" tissue. Applicant also notes that this claim amendment does not cause the claim to positively recite a tissue, thus the claim is in full compliance with 35 U.S.C. 101. Applicant submits that the pending claims fully comply with §112.

**The Prior Art Based Rejections**

*§102(b) Based on Stenberg*

Claims 1-5, 7, 8, and 19 are rejected as being anticipated by Stenberg (U.S. Patent No. 4,010,795). Applicant submits that the rejection of these claims as being anticipated by Stenberg is obviated due to the amendment to claim 1 that requires a first temperature sensing element that is effective to measure the temperature of the target tissue. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

*§103 Based on Stenberg in view of Daily*

The Examiner also rejects claims 6 and 9-11 as being obvious over Stenberg in view of U.S. Patent No. 5,609,620 (Daily). The Examiner argues that Stenberg teaches all limitations of claim 6, except for the limitation requiring that the implantable member be formed from a silicone elastomer. Daily is combined with Stenberg because the Examiner alleges that Daily discloses a device for thermally affecting tissue that may be formed from a silicone elastomer. With regard to claims 9-11, the Examiner argues that Stenberg teaches all limitations of these claims except for the backing member, which, according to the Examiner, is taught by the Daily reference.

Applicant submits that this rejection is obviated by the amendments to claim 1, which now requires the apparatus to have a first temperature sensing element that is effective to measure the temperature of the target tissue. No such feature is disclosed in either Stenberg or Daily, and Applicant submits that this rejection is improper and should now be withdrawn.

*§103 Based on Stenberg in view of Goble*

Claims 12-18 stand rejected as being obvious over Stenberg in view of U.S. Patent No. 5,891,134 (Goble). In support of this rejection, the Examiner argues that Stenberg teaches all limitations of claims 12 and 13, except for the temperature measurement element. Goble is thus relied upon by the Examiner as allegedly teaching "an apparatus for thermally affecting tissue including a temperature measurement element 66 positioned in the fluid-tight lumen of the device and a temperature indication element in the control unit 14 for indicating the temperature of the thermally transmissive fluid of the device." The Examiner argues that it would have been obvious to have included the temperature measurement system of Goble and a device of Stenberg "in order to ensure the device is working properly and that contacted tissue is not adversely affected by the temperature of the device." With regard to claim 14, the Examiner argues that the combined device of Stenberg and Goble "teaches all of the limitations in this claim . . . except for the temperature measurement element being positioned between the implantable member and the tissue in order to indicate the temperature of the tissue." The Examiner argues that it would have been obvious that the temperature measurement element of the combined device of Stenberg and Goble "could have been placed between the implantable member and the tissue in order to monitor temperature of the tissue so that it is not permanently harmed during a procedure." Regarding claims 15-18, the Examiner argues that Stenberg teaches all limitations of these claims except for the pressure measurement device. The Examiner argues that Goble teaches an apparatus for thermally affecting tissue that includes a pressure sensor 58 and a pressure warning alarm 62. The Examiner argues that it would have been obvious to include a pressure measurement element between the implantable member and the tissue in the Stenberg device "to ensure that the pressure exerted by the device does not harm surrounding tissue."

Applicant respectfully traverses this rejection and submits that the rejection of claims 13 and 14 is moot since these claims have been canceled. Further reasons in support of the allowability of these claims are noted below. First, claim 1, as noted above, has been amended to require a first temperature sensing element that is effective to measure the temperature of the target tissue. The Examiner acknowledges that this element is not disclosed or suggested by the

Stenberg reference and in the Office Action the Examiner relies upon Goble to teach or suggest a temperature measurement element. Applicant submits that the reliance on Goble to reject any of the pending claims, particularly claims 1 and 12-18, is misplaced.

Claim 1, as noted above, requires that there be a first temperature sensing element that is effective to measure the temperature of the target tissue. Goble makes no mention or suggestion of any element that measures the temperature of tissue. Goble is instead directed to a device and a system used to apply thermal energy to tissue to ablate uterine tissue such as for purposes of endometrial ablation. The Goble device has a distendable bladder which has an electrode assembly positioned therein. The bladder is filled with a conductive fluid such as saline. In use, the bladder is inflated by the addition of the fluid. The electrodes, which may be bipolar electrodes, are activated to heat the fluid within the vessel and, in turn, heat the bladder wall which will ablate the uterine tissue that it contacts. The Goble reference does not disclose measuring the temperature of tissue and such a measurement apparently would not be necessary due to the unique treatment concept disclosed by Goble. Various locations of the uterine tissue will be at different temperatures, as a result of the disease state of the tissue and/or the progress of the ablation. Thus, the only temperature measurement disclosed by Goble is directed to the temperature of the fluid within the lumen.

Contrary to the Examiner's arguments, there is nothing in either Stenberg or Goble that teaches the measurement of tissue temperature with a temperature sensing element. Moreover, there is no suggestion in either one of these references that any sort of feature would be useful or necessary. In fact, such a feature would be useless and meaningless in the device of Goble since the tissue that is contacted by the inflatable ablation balloon of Goble is at a variety of different temperatures. For these reasons, Applicant submits that claim 1, as now amended, fully distinguishes over the combination of Stenberg and Goble. The remaining rejected claims that are still pending, i.e., 12 and 15-18, depend directly or indirectly from claim 1 and distinguish over this combination of references by virtue of their dependency from claim 1.

Applicant also submits that the combination of Stenberg and Goble fails to disclose or suggest a pressure measurement element that is effective to measure the pressure at which an implantable member is applied to the target tissue. The Goble device includes a pressure sensing element, but this element measures only the pressure of fluid within the inflatable balloon to

ensure that the balloon does not burst while treating a patient. Although the surface of the balloon is placed in contact with patient tissue, Goble fails to disclose or suggest any use of a pressure sensing device to sense the pressure at which an implantable member is applied to the target tissue.

Applicant submits that new claim 48 distinguishes over the cited art because it requires an implantable member having an outer surface configurable to contact target tissue wherein the implantable member is formed of a shape memory material that can be deformed to a first shape upon the application of a force in which returns to an at-rest shape upon removal of the force. Stenberg does not disclose any such device. Rather, Stenberg merely discloses a malleable material that can be deformed to a desired shape. Once the deforming force is removed, the device does not return to its original shape; it remains in its deformed condition.

New claim 49 also distinguishes over the cited art because it is directed to an apparatus for thermally affecting tissue, comprising an implantable member having an outer surface configurable to contact target tissue; at least one fluid tight lumen defined by the implantable member, the fluid tight lumen being in thermal communication with the outer surface of the implantable member and it being configured to receive a thermally transmissive fluid to thereby impart a temperature-reducing thermal change to the outer surface of the implantable member; and a temperature sensing element disclosed within the lumen that is effective to measure the temperature of any fluid within the lumen.

Neither Stenberg nor Goble, or a combination thereof, disclose such a device that includes both a temperature sensing element that is effective to measure the temperature of any fluid within the lumen and which is able to impart a temperature reducing thermal change to the outer surface of implantable member. Stenberg does not disclose any sort of temperature sensing element and Goble only discloses a device that uses electrical energy to heat a conductive fluid within a balloon and, in turn, heat the surface of the balloon.

In view of the foregoing remarks, Applicant submits that the pending claims fully distinguish over the cited references and respectfully requests that all rejections be withdrawn.

The Examiner is urged to telephone the undersigned attorney for Applicant in the event that such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

By _____

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